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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,441	01/11/2002	Bernard A. Gonzalez	57287US002	8431
32692	7590	12/20/2004	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY			CHIN, BRAD Y	
PO BOX 33427			ART UNIT	
ST. PAUL, MN 55133-3427			PAPER NUMBER	

1744

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,441

Applicant(s)

GONZALEZ ET AL.

Examiner

Brad Y. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/11/02, 4/3/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Applicant should remove the word, "and" from line 6 of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirckof [U.S. Patent No. 6,488,890].

Kirckof teaches a system for determining the efficacy of a sterilization process and communicating that determination to a remote location, the system comprising:

a sterilization sensor comprising an indicator that undergoes an optical change when exposed to an efficacious sterilization process (sterilization indicator 10 including sterilizing agent sensitive inks that changes color, i.e. the indicator (1) changes to a color close to the color of the backing or clear or (2) changes from one color (e.g. purple) to another color (e.g. green) when exposed to an efficacious sterilization process, i.e. exposure to a steam sterilization cycle);

a reader adapted to receive the sterilization sensor (scanning [apparatus] means of sterilizer 20 adapted to receive the sterilization sensor information – See Fig. 17; See Specification, col. 15, lines 32-54); the reader comprising

an illumination source for illuminating the sterilization sensor (illumination source 82 may provide any suitable source of energy such as radiation, light, or other suitable beam);

a first color sensor for evaluating the condition of the illuminated sterilization sensor (detector 83 detects energy reflected from the sterilization indicator 10 and its corresponding color change);

an interpretation circuit for interpreting the output of the color sensor to determine whether the optical change has taken place (detector 83 in conjunction with controller/processor 81 – differences in reflections are translated into electrical signals by a light detector in the scanner – See Specification, col. 16, lines 45-50; device is particularly suitable for reading and interpreting colormetric chemical indicators 10 – See Specification, col. 17, lines 30-35); and

a communication circuit for communicating data from the interpretation circuit to the remote location ([1] output component 84 including any suitable means known in the art including but not limited to display lights, computer displays, graphical user interfaces or further communication to additional electronic hardware – See Specification, col. 15, lines 41-44, i.e. includes circuitry which allows communication of data from the detector 83 in conjunction with the controller/processor 81 to an output component 84 in a remote location, e.g. computer display or graphical interface for use in an integrated electronic record keeping and sterilization monitoring system – See Specification, col. 18, lines 62-67; and [2] various components in communication (e.g. electronic communication) by means of electronic wiring, wireless communications, internet or intranet connections and/or Ethernet connections – See Specification, col. 19 line 66 to col. 20, line 3).

Regarding claim 3, Kirckof teaches the system according to claim 1 further comprising an interrogator for commanding the reader to communicate data from the interpretation circuit (system of components, e.g. hardware and software, for use in an integrated sterilization

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monitoring and inventory tracking system – hardware and software would function as an interrogator for commanding the reader to communicate data from the interpretation circuit, allowing the user to monitor articles subjected to a sterilization process – See Specification, col. 19, lines 1-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claim 2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirckof [U.S. Patent No. 6,488,890].

Kirckof teaches the system for determining the efficacy of a sterilization process and communicating that determination to a remote location as defined in claim 1 above.

Regarding claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the sterilization sensor to be disposable because chemical indicators, such as those used in Kirckof, are inexpensive and primarily serve as a single-use determination of the efficacy of a sterilization process or a change in environmental conditions.

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On the other hand, it would have been obvious for the reader to be reusable because of the complexity of the electronics and software involved with the functionality of Kirckof's scanning means, i.e. the reader. Accordingly, it would be more economical and practical for the reader to be reusable, allowing the user to evaluate numerous chemical indicators and numerous sterilization processes with a single reader.

Regarding claim 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the system according to claim 1 to further comprise a second color sensor for evaluating the condition of the illuminated sterilization sensor, wherein the interpretation circuit interprets the output of the first color sensor and the second color sensor to determine whether the optical change has taken place because it would have been obvious to incorporate more than one color sensor for evaluating the condition of the illuminated sterilization sensor (Duplicating part for a multiple effect – *In re Harza*, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960)) to increase the accuracy of interpreting the color change or lack thereof of the sterilization sensor. Incorporating a second color sensor would allow the user to verify the correctness of the first sensor's determination of whether an optical change has actually occurred on the sterilization sensor.

Regarding claim 5, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the system according to claim 1 wherein the reader has at least one tortuous path adapted for conveying gas to the sterilization sensor because it would have been obvious that to obtain an accurate reading of the chemical indicator for the determination of the efficacy of a sterilization process, it would have been necessary to control the duration and the means for which the gas would react with the chemical indicator.

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4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn [U.S. Patent No. 3,982,893] in view of Kirckof [U.S. Patent No. 6,488,890].

Joslyn teaches a method for determining the efficacy of a sterilization process (a sterilization control and more particularly to a device which may be placed within a sterilizing chamber for continuously monitoring the various sterilization affecting environmental conditions, [e.g. the efficacious nature of a sterilization process], using information generated by such device to control operation of the sterilizer – See Specification, col. 1, line 6-12), comprising the steps of:

providing a sterilization sensor comprising an indicator that undergoes a change when exposed to an efficacious sterilization process (plurality of sensing members 40, 42, and 43 capable of translating a particular environmental condition into a representative electrical signal such as voltage or current; any change in the condition will then produce a corresponding voltage or current change, so that a continuous monitoring of the environment is possible – See Specification, col. 2, lines 57-65);

placing the sterilization sensor within a reader (plurality of sensing members 40, 42, and 43 in monitor-transmitter 16);

placing the reader with the sterilization sensor inside a package of goods (See Specification, col. 3, lines 58-67 – in operation, the device 16 is simply wrapped with or placed within one or more of the goods 14 to be sterilized and the goods placed within sterilizing chamber 12. During the sterilizing cycle, device 16 will indicate the environment conditions existing at the heart of the load to be sterilized);

subjecting the package to sterilizing conditions (See Specification, col. 3, lines 58-67 – in operation, the device 16 is simply wrapped with or placed within one or more of the goods 14 to be sterilized and the goods placed within sterilizing chamber 12. During the sterilizing cycle,

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device 16 will indicate the environment conditions existing at the heart of the load to be sterilized); and

interrogating the reader without opening the package to learn whether the optical change has taken place (See Specification, col. 3, lines 57-67 – The signals emanating from the device are received by the receiving antenna 18 which in turn conveys the information from the sterility indicator 20 and from there to the sterilizer controller 22; See Specification, col. 4, lines 1-10 The sterility indicator and sterilizer control allow the user to control the sterilizing conditions that the package of goods are undergoing, allowing the user to make necessary adjustments in the sterilizer environment. Thus, it would seem that the user would be able to use the sterilizer control to interrogate the reader, allowing the user to identify the conditions within the package without having to open the package, i.e. whether the sterilization conditions have been met).

Joslyn fails to teach a method where the sterilization sensor comprises an indicator that undergoes an optical change when exposed to an efficacious sterilization process.

Kirckof teaches the method for determining the efficacy of a sterilization process and communicating that determination to a remote location (See explanation for claim 1 above). Kirckof incorporates the use of a sterilization sensor, which utilizes a color-changing chemical indicator to indicate the efficacy of a sterilization process.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the method of Kirckof for providing a sterilization sensor comprising an indicator that undergoes an optical change when exposed to an efficacious sterilization process for the method of Joslyn's system because Joslyn's system requires providing a sensor means for continuously monitoring a plurality of sterilization affecting environmental conditions within a load. Joslyn's system translates the sensing means into an electrical signal for interpretation and communication to a remote system. Kirckof provides such a sensor means through the use

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of a sterilization sensor comprising an indicator that undergoes an optical change when exposed to changing environmental conditions. The sterilization indicator is illuminated to interpret the color change of the indicator and translated into an electrical signal for communication to a remote system.

Regarding claim 7, Joslyn and Kirckof teach the method defined in claim 6 above. Joslyn further teaches the method according to claim 6 wherein the reader comprises a communication circuit for communicating data from the interpretation circuit to a location outside the package (See explanation for claim 1 above).

Joslyn fails to teach the method where the reader comprises an illumination source for illuminating the sterilization sensor, a color sensor for evaluating the condition of the illuminated sterilization sensor, and an interpretation circuit for interpreting the output of the color sensor to determine whether the optical change has taken place.

Kirckof teaches each of the missing aspects of claim 7 that Joslyn fails to teach (see explanation for claim 1 above).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the reader of Kirckof comprising an illumination source, color sensor, and interpretation circuit into Joslyn because Kirckof's sterilization sensor and the reader, along with these components, would allow the user of Joslyn's system to evaluate and determine the efficacy of a sterilization process on an unopened package of goods.

Regarding claim 8, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the sterilization sensor to be disposable because chemical indicators, such as those used in Kirckof, are inexpensive and primarily serve as a single-use

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determination of the efficacy of a sterilization process or a change in environmental conditions. On the other hand, it would have been obvious for the reader to be reusable because of the complexity of the electronics and software involved with the functionality of Kirckof's scanning means, i.e. the reader. Accordingly, it would be more economical and practical for the reader to be reusable, allowing the user to evaluate numerous chemical indicators and numerous sterilization processes with a single reader.

Conclusion


5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
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